

## **REMARKS/ARGUMENTS**

Claims 1, 3, and 6 have been amended in compliance with the Examiner's recommendations. Support for amended claims 1 and 3 is found in the originally filed claims and in Examples 1 and Example 5 on pages 32 and 38 of the specification. Claims 10-11 have been amended. Support for amended claims 10-11 is found on page 6, lines 5-7 of the specification. Amended claims 1, 3, 6 and 10-11 and claims 2, 4-5, and 7-9 are pending.

### **Sequence compliance**

The specification has been amended to include a Sequence Listing and proper reference to the sequences therein and to correct minor typographical errors. The amendments are made in adherence with 37 C.F.R. § 1.821-1.825. This amendment is accompanied by a floppy disk containing the above named sequence, SEQUENCE ID NUMBERS 1-2 in computer readable form, and a paper copy of the sequence information. The computer readable sequence listing was prepared through use of the software program "PatentIn" provided by the PTO. The information contained in the computer readable disk is identical to that of the paper copy. This amendment contains no new matter. Applicant submits that this amendment, the accompanying computer readable sequence listing, and the paper copy thereof serve to place this application in a condition of adherence to the rules 37 C.F.R. § 1.821-1.825. Entry of this amendment is respectfully requested.

### **Claim Rejections – 35 U.S.C. § 101**

Claims 10-11 are rejected under 35 U.S.C. § 101 because the Examiner alleges the claimed invention is directed to non-statutory subject matter wherein the claims read on a

“product of nature.” In particular, the Examiner asserts that the claims are directed to shrimp and prawn populations which are genetically and phenotypically normal.

Amended claim 10 recites a population of shrimp or prawns having a skewed percentage of females to males produced according to the method of claim 6, wherein said percentage of females is greater than about 80%.

Amended claim 11 recites a population of shrimp or prawns having a skewed percentage of females to males produced according to the method of claim 6, wherein said percentage of females is greater than about 90%.

Applicant respectfully traverses.

The *Malecha, et al.* reference cited by the Examiner discloses that the female to male sex-ratio of freshwater prawn (*e.g., Macrobrachium rosenbergii*) progeny resulting from normal (*e.g., wild-type*) crosses is 1.29:1.0 wherein the percentage of females is 56% and the percentage of males is 44% (*see e.g., abstract, page 205, and Table 4.A*). The amended claims, as distinguished from the reference, recite prawn populations having female to male sex-ratios wherein the percentage of females is greater than about 80% (claim 10) and greater than about 90% (claim 11). Applicant’s claims recite prawn populations having female to male sex-ratios wherein the percentage of females (*e.g., in excess of 80% and in excess of 90%*) is substantially greater than the percentage of females present in wild type prawn populations (*e.g., 56%*). In addition, it is commonly known in the art that populations consist of organisms located in a specified habitat from which a statistical sample is obtainable. The female to male sex ratio derived from a statistical sample of prawns in the population of prawns found in nature is substantially different from the female to male sex ratio derived

from a statistical sample of the prawns that are produced by the methods recited in the claims. In particular, dependent claims 10-11 recite prawn populations having sex ratios which are not found in nature and which are not reproducible by crossing wild-type male and wild-type female prawns. Moreover, the “collecting” and “sexing” of shrimp and prawns, in contrast to the Examiner’s assertions, are artificial processes which do not occur in nature. For the foregoing reasons, Applicant’s claims recite patentable subject matter, which is not found in nature, and Applicant therefore requests that the Examiner’s rejection of amended claims 11 and 12 under 35 U.S.C. 101 be withdrawn.

**Claim Rejections – 35 U.S.C. § 112, First Paragraph**

Claims 1 and 3 (and claims 4 and 5 which depend therefrom) are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter not described in the specification in order to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

Amended claim 1 recites a composition consisting essentially of an isolated shrimp or prawn androgenic polypeptide that is capable of producing a sexually reproductive neomale shrimp or prawn.

Amended claim 3 recites a method of producing a sexually reproductive neomale shrimp or prawn comprising treating a shrimp or prawn with a composition consisting essentially of an androgenic peptide for producing a sexually reproductive neomale shrimp or prawn.

The Examiner states that because the specification does not disclose the isolation of androgenic peptides from prawn species other than *Macrobrachium rosenbergii* and does not disclose the isolation of androgenic peptides from shrimp species other than *Panaeus vannemei*, the claims are not supported by the specification.

Applicant respectfully traverses.

The Examiner has the initial burden of presenting the evidence or reasons establishing why the skilled artisan would not recognize a description of the invention defined by the claims in Applicant's disclosure. *In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976); *Ex parte Sorenson*, 3 USPQ2d 1462, 1463 (Bd. Pat. App. & Inter. 1987). Applicant maintains that the Examiner has not met this burden and directs the Examiner's attention to MPEP II.A (8th Edition, August 2001) §2163 stating:

There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)....Consequently, rejection of an original claim for lack of written description should be rare. MPEP § 2163 (II.A).

The specification describes the isolation of male androgenic sex hormone from prawns and shrimp, use of the neomale for producing populations of prawns and shrimp containing large number percentages of females relative to the number of male prawns and shrimp, and methods for cloning the gene encoding the androgenic sex hormone. All of these methods are applicable to the isolation and/or cloning of the androgenic sex hormone from other species of shrimp and prawns.

Applicant has further provided detailed instructions for isolating androgenic sex hormone from the androgenic glands of male prawns (e.g., *Macrobrachium rosenbergii*)

wherein the dissected androgenic glands are incubated in petri dishes containing defined media and androgenic sex hormone is released from androgenic glands into a defined media. The Examples further demonstrate the isolation and sequencing (*see e.g.*, page 32, lines 23-37 and page 33, lines 1-8 of the specification) of male androgenic sex hormone from one species of prawn. As indicated previously, these methods are applicable to other species of prawns for practicing Applicant's invention.

The Examples show that when female prawns are injected with isolated androgenic sex hormone, neomale prawns are formed. Androgenic sex hormone injected into the ventral area (*e.g.*, between fifth walking leg and first tail segment) of nine female prawn recipients produced three adult neomale prawns. The prawns were sexed based on the appearance of a molted exuvium exoskeleton. As indicated in Table 1 (page 37, line 4 of the specification), six out of the seven surviving injected prawns showed development of an appendix masculina (*e.g.*, *see* Figs. 3-5). Of the six neomaskulinized females identified, three developed into adult neomale prawns (page 37, lines 34-37).

The specification further shows that female post larvae *Penaeus vannamei* marine shrimp placed in wells containing sea water and "challenged" by placement of two dissected androgenic glands into each well developed into neomales. (*see e.g.*, page 38, lines 4-11, 8-22, and 27-29 and page 40, lines 1-7 and 21-26 of the specification). The shrimp were sexed based on the appearance of external male genitalia on the first pleopod and the appearance or absence of the appendix masculina on the second pleopod. The data in Table 3 (*e.g.*, page 41 lines 11-19) of the specification show that female post larvae immersed in the material secreted by androgenic glands displayed a 2:1 ratio skewed in the favor of neomales. As

indicated herein, these methods are applicable to other species of shrimp for practicing Applicant's invention.

For the foregoing reasons, Applicant respectfully requests that the rejection of amended claims 1 and 3 (and claims 4 and 5 which depend therefrom) for lack of written description under 35 U.S.C. §112, first paragraph be withdrawn.

**Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

Claim 6 (and claims 7-10 which depend therefrom) are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claim 6 in compliance with the Examiner's recommendations to recite a skewed ratio of females to males. Accordingly, Applicant requests that the rejection of claim 6 (and claims 7-10 which depend therefrom) be withdrawn.

**Claim Rejections – 35 U.S.C. § 102(b) As Being Anticipated by *Malecha, et al.***

Claims 1, 3 (and claims 4-5 which depend therefrom) and 10-11 are rejected under 35 U.S.C. § 102(b) as being as being anticipated by *Malecha, et al.* In particular, the Examiner maintains that *Malecha* teaches the isolation of androgenic glands from male prawns (*e.g.*, *Macrobrachium rosenbergii*) and the implantation of androgenic glands into juvenile female prawn recipients for producing sexually reproductive neomales. The Examiner further maintains that the reference teaches androgenic glands which produce a hormone that is

responsible for the differentiation of primary and secondary male sexual characteristics. The Examiner concludes that the disclosure in *Malecha* anticipates Applicant's claims.

Applicant respectfully traverses.

Applicant has amended claim 1 to recite a composition consisting essentially of an isolated shrimp or prawn androgenic polypeptide capable of producing a sexually reproductive neomale shrimp or prawn, as recommended by the Examiner.

Applicant has amended claim 3 to recite a method of producing a sexually reproductive neomale shrimp or prawn comprising: treating a shrimp or prawn with a composition consisting essentially of an androgenic peptide to produce a sexually reproductive neomale shrimp or prawn, as recommended by the Examiner.

Support for amended claims 1 and 3 is found in the originally filed claims and in Examples 1 and 5 on pages 32 and 38 of the specification.

Applicant maintains that *Malecha* does not anticipate the amended claims since the reference teaches the isolation and implantation of androgenic glands, while Applicant's amended claims require a composition consisting essentially of androgenic hormone. Accordingly, *Malecha* does not teach all of the limitations of the amended claims.

Amended claim 6 (from which claims 10 and 11 depend) recites a neomale shrimp or prawn which does not contain transplanted androgenic tissue. *Malecha*, in contrast to Applicant's amended claims, teaches the reversal of sex in fresh water prawns achieved by implanting androgenic gland tissue from adult males into very young putative females (see e.g., abstract). Accordingly, the reference teaches away from Applicant's invention in that the neomales produced in *Malecha* originate from putative females implanted with androgenic

tissue, although Applicant's claims require neomales which do not contain this implanted tissue. Accordingly, the teachings of *Malecha* do not anticipate all of the elements of Applicant's claims and Applicant therefore requests that the Examiner's rejection under 35 U.S.C. 102(b) of amended claims 1, 3 (and claims 4-5 which depend therefrom) and amended claims 10-11 be withdrawn.

**Claim Rejections – 35 U.S.C. § 102(b) As Being Anticipated by *Nakashima, et al***

Claims 10-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Nakashima, et al*. In particular, the Examiner states that *Nakashima* teaches a single female shrimp housed in a holding container.

Applicant respectfully traverses.

Applicant points out that claims 10 and 11 depend from claim 6 and accordingly require a population of shrimp or prawns having a skewed percentage of females to males wherein the population is produced by breeding a neomale shrimp or prawn with a corresponding female shrimp or prawn. As distinguished from Applicant's claims, *Nakashima* neither teaches nor discloses the breeding of a neomale shrimp or prawn with a corresponding female for producing a population of shrimp or prawns wherein the percentage of females to males is skewed. In particular, the breeding of neomales with corresponding females produces a population which contains a large number of female shrimp or prawns. *Nakashima*, in contrast, teaches a single female shrimp that is housed in a container. As discussed herein, the skilled artisan knows that a population comprises organisms located in a specified habitat from which a statistical sample is obtainable. As distinguished from the populations of shrimp produced by the methods recited in the claims, a single female shrimp



placed in a container for keeping separate from a male shrimp (*see e.g.*, page 150) does not comprise a population of shrimp in a habitat from which an accurate statistical sample is obtainable.

For the foregoing reasons, *Nakashima* fails to teach or suggest a shrimp population, much less a shrimp population produced by breeding a neomale with a corresponding female, as required by the claims. Accordingly, *Nakashima* fails to teach the limitations of Applicant's claims and Applicant respectfully requests that the Examiner's rejection under 35 U.S.C. 102(b) of amended claims 10-11 be withdrawn.

**Claim Rejections – 35 U.S.C. § 102(b) As Being Anticipated by *Merk* (EP 0514015A1)**

Claim 2 is rejected under 35 U.S.C. § 102(b) as being anticipated by *Merk* (EP 0514015A1). In particular, the Examiner maintains that *Merk* teaches a shellfish that is genotypically female but phenotypically male wherein the shellfish may be either a shrimp or prawn. The Examiner maintains that the *Merk* shellfish anticipates the sex-reversed sexually reproductive neomale shrimp or prawn recited in claim 2.

Applicant respectfully traverses.

*Merk* teaches shellfish treated with steroid biosynthesis inhibitors or antagonists which prevent the conversion of androgens to estrogens. The resulting absence of estrogen results in the conversion of genotypic female shellfish into phenotypic male shellfish (*see e.g.*, abstract). As distinguished from *Merk*, claim 2 teaches a sexually reproductive neomale shrimp. Applicant is unaware of any disclosure in the reference which teaches a phenotypic male shellfish which is demonstrated to be sexually reproductive, as required by claim 2.

Accordingly, *Merk* fails to teach all of the limitations of claim 2. Applicant therefore requests that the Examiner's rejection under 35 U.S.C. 102(b) of claim 2 be withdrawn.

### **Conclusion**

Applicant respectfully submits that the claims are now in condition for allowance. If upon, review, the Examiner feels there are additional outstanding issues, the Examiner is invited to direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,

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